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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,568	07/24/2003	Ronald C. Montelaro	I 2000.608 US C1	3285

31846 7590 06/28/2005

INTERVET U.S.  
PATENT DEPARTMENT  
PO BOX 318  
MILLSBORO, DE 19966-0318

EXAMINER
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LI, BAO Q

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/627,568

Applicant(s)

MONTELARO ET AL.

Examiner

Bao Qun Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-10 and 14-16 is/are pending in the application.
- 4a) Of the above claim(s) 11-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-10 and 14-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of group I, claims 1-10, 14-15 in the reply filed on October 30, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement is still deemed proper and is therefore made FINAL.

### ***Response to Amendment***

2. The amendment filed 05/27/05 has been acknowledged. Claims 1 and 14-15 have been amended. Claim 2 has been canceled. New claim 16 has been added. Claims 1 and 3-16 are pending. Claims 1, 3-10 and 14-16 are considered before the examiner.

### ***Sequence requirements***

3. This application contains sequence disclosures in **Figs. 2a-2b, 6-7 and 9** that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

4. Full compliance with the sequence rules is required in response to this Office Action. A complete response to this office action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this office action will be held non-responsive.

### ***Specification***

5. In line 8 of page 31, please complete the citation of the reference by Hammond et al. because the year of the publication is missing.

### ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 2-10, 14-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, the rejection is directed to that applicants do not have a possession for having a genetically engineered EIAV construct comprising two inserted stop codons and a deletion in the S2 gene.

8. In the instant case, the specification only teaches that the following EIAV mutants (See Fig. 2a): 1). EIAV.G5/s, an EIAV mutant comprising one substitution mutation of replace the G5 a stop codon in the S2 gene; 2). EIAV.2M/X, an EIAV mutant with three substitutive mutation at M16 and G5 and G18 in S2 gene, wherein the M16, G5 and G18 are replaced with T and another two stop codons respectively; 3). EIAV.deltaS2, an EIAV mutant with a deletion of the first 5 nucleotides of S2 gene, and EIAV.Q56/s, an EIAV mutant having a substitutive mutation at Q56, in which the amino acid residue Q56 is replaced with a stop codon.

9. However, there is no disclosure of an EIAV mutant comprising two stop codons insertion plus a deletion with 6-25 nucleic acids in the S2 gene.

10. Vas-Cath. V. Makurkar, 19USPQ2d 111, clearly states "applicant must convey with reasonable clarity to those skilled in the art, as of the filing date sought, he or she was in possession of the invention. The invention is, for purpose of the 'written description' inquiry, whatever is now claimed." (See page 1117). The specification does not "clearly allow person of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). Moreover, to be in the possession of any claimed invention, the applicants must show that a significance of conception and reduction to practice was reached before the application was filed. The case law has also made it clear that the requirements for a "written description" and an "enabling disclosure" are separate. The satisfaction of the enablement requirement does not satisfy the written description requirement. See *In re Barker*, 559 F.2d 588,

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591, 194 USPQ 470, 472 (CCPA 1977) (a specification may be sufficient to enable one skilled in the art to make and use the invention, but still fail to comply with the written description requirement). See also *In re DiLeone*, 436 F.2d 1404, 1405, 168 USPQ 592, 593 (CCPA 1971). For the written description requirement, an applicant's specification must reasonably convey to those skilled in the art that the applicant was in possession of the claimed invention as of the date of invention. Thus, a specification contains sufficient information to enable a skilled chemist to produce a particular compound, but it makes no reference to the compound in question, the "written description" requirement is still not met even though the description may be enabling.

11. At the present case, while the specification has described four kinds of EIAV mutants, the claimed EIAV mutant(s) having at least 5 to 25 nucleotides deletion in addition to the insertion of two redundant stop codons insertions as current pending claims drafted has never been described. Neither do applicants teach there is any contemplation of making such combination of mutations in the specification. Therefore, claims 1, 3-9,10 and 14-16 are rejected due to the application do not have the possession of claimed subject matter.

#### ***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 3, 4, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (A) (J. Virol. 1998, Vol. 72, No. 10, pp. 8344-8348).

14. Li et al. (A) teach a genetically engineered EIAV construct, i.e. EIAV.2M/X that comprising insertions of two redundant stop codons at the positions G5 and G16 and a deletion of the original amino acid methenion at position 16 and replace it with Threonion in S2 gene (Fig. 1 on page 8345), wherein the mutations in S2 gene made the EIAV unable to express the S2 gene but it does not interrupt the EIAV envelope protein expression after the mutated EIAV is replicated in host cells (See 1<sup>st</sup> column of page 8346). Because the mutated EIAV lacking S2

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gene expression is inherently different from the wild type EIAV virus since the wild-type EIAV is able to express the S2 gene, the claims are anticipated by the cited reference.

***Claim Rejections - 35 USC § 102***

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

16. Claim 21 is rejected under 35 U.S.C. 102(a) as being anticipated by Li et al. (B) (J. Virol. January 2000, Vol. 74, No. 1, pp. 573-579).

17. Li et al. (B) disclosed an immunogenic composition comprising the genetically engineered EIAV construct, i.e. EIAV.2M/X as described above. Therefore, the claimed invention is anticipated by the cited reference.

(It should be noted that the specification has described several substitution mutations. However, applicants do not describe any mutation as a substitutive mutation, rather, applicants describe the mutation as an insertion. During prosecution of a very related case 10,369,792, the examiner has raised a similar question. In response to the examiner's request, Applicants disclaims that the substitution mutation in that case is referred to the mutations of a deletion of the original nucleic acid or amino acid and an insertion of another nucleic acid code or amino acid residue. To this context, the above rejections applied. However, if applicants refer the deletion and insertion occurring in different genetic codes, please clarify in response to this office Action).

***Conclusion***

No claims are allowed.

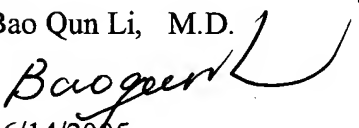
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li, M.D.

  
06/14/2005